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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,156	11/14/2003	Mitchell I. Kirschner	718689	2373

7590 06/17/2004

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EXAMINER

CHOI, FRANK I

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/714,156	<b>Applicant(s)</b> KIRSCHNER ET AL.	
	<b>Examiner</b> Frank I Choi	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/9/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hermelin et al. (US Pat. 6,258,846) or Abbruzzese et al. (US Pat. 6,077,828), each in view of the acknowledged prior art, Opheim (US Pat. 6,346,231), Manufacturing Chemist & Aerosol News and Cuca (US Pat. 4,656,028).

Hermelin et al. teach nutritional supplements for women comprising soft gelatin capsules containing linoleic acid, linolenic acid and docosahexaenoic acid, derived from plant or fish oils, other vitamins, such as vitamin E, minerals, folic acid, including folic acid in a controlled release form (see entire document). It is taught that calcium is preferably present in the composition and embodiments art taught containing calcium (Column 12, lines 16-25, Column 16, lines 35-68, column 17, lines 1-25, 60-68, Column 18, lines 1-16)

Abbruzzese et al. teach a nutrition supplement containing mixture of omega-6 and omega 3 fatty acids, having 12-24 carbons, such as linoleic, linolenic, eicosapentaenoic, docosapentaenoic and docosahexaenoic acid, vitamin D, Vitamin E, folic acid and calcium, which can be administered in capsules (See entire document, especially, Column 3, lines 10-43, column 4, lines 36-55, Column 5, lines 25-40, Column 7, lines 44-68, columns 8-20).

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Applicant acknowledges that in women in pregnancy have digestive disturbances, including heartburn, gastroesophageal reflux, dyspepsia, regurgitation and increased sensitivity to unpleasant odors and/or tastes (Pg. 1, lines 14-25).

Opheim teaches the use of soft gelatin capsules to improve the palatability of fish oils, such as EPA and DHA (See entire document).

Manufacturing Chemist & Aerosol News teaches that soft gelatin capsules containing omega-3-fatty acids are easy to swallow (Abstract).

Cuca teaches the encapsulation of calcium carbonate in soft gelatin capsules which is used as an antacid (Columns 1,2)

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a formulation containing linolenic and linoleic acid and other omega fatty acids and calcium compounds. However, the prior art amply suggests the same as the prior art discloses nutritional composition which contain linolenic, linoleic and other omega fatty acids and vitamins and minerals, including vitamins E and D, folic acid and calcium, overcoming the unpleasant taste of omega-3-fatty acids by using soft gelatin capsules, that soft gelatin capsules containing omega-3-fatty acids are easy to swallow, that calcium compounds are suitable for use in nutritional formulations and that calcium carbonate antacids can be formulated in soft gelatin capsules. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that a soft gelatin capsule containing linolenic acid, linoleic acid and other omega-3-fatty acids and vitamins and minerals, including vitamins E and D, folic acid and calcium would well tolerated by the patient.

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant indicates that it reaffirms traversal of the rejection which was set forth in now abandoned Application Serial No. 09/972,664. However, Applicant never responded to the rejection in said application.

Applicant additionally maintains that it is entitled to the May 27, 1999 filing date of the 09/320559 Application. However, this application is only an indirect continuation-in-part of the '559 Application. As such, any claims which contain subject matter which was not enabled or disclosed in the '559 application are not entitled to the May 27, 1999 filing date. For instance, to the extent the claims contain the omega fatty acids, said claims are not entitled to the May 27, 1999 filing date as they contain subject matter which does not appear to have been disclosed or enabled by the '559 application. As such, the rejection herein is applicable to the claims herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

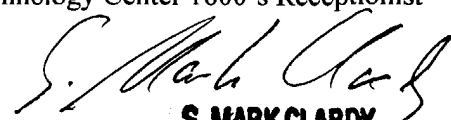
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

June 14, 2004



**S. MARK CLARDY**  
**PATENT EXAMINER**  
**GROUP 1200**